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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TSAY, MARSHA M	
ART UNIT	**PAPER NUMBER**
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,445	WANG ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *132-146,148-154 and 171-176* is/are pending in the application.

4a) Of the above claim(s) *148-154* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *132-146 and 171-176* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/31/05; 02/22/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election with traverse of Group I, claims 132-146, 171-176, to SEQ ID NOS: 1, 2 in the reply filed on September 25, 2007 is acknowledged. The traversal is on the ground(s) that polypeptides having chaperone-like activity and the polynucleotide sequences encoding them, as taught in claims 132-146, correspond to the proteins having the structure and functions (chaperone-like activity) as taught in claims 147-170. This is not found persuasive because the specific SEQ ID NOS. recited in Group I are absent in Group II and do not constitute as a special technical feature of Group II. Therefore, since each Group requires a special technical feature not shared with the other, they lack unity of invention and are separate inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claims 148-154 have been withdrawn from further consideration by the Examiner because they are drawn to non-elected inventions. Claims 132-146, 171-176, to SEQ ID NOS: 1, 2, are currently under examination.

Priority: The benefit date is September 4, 2002, for the purpose of prior art.

Claim Objections

Claims 133-134, 138-139, 143-144 are objected to because of the following informalities: the instant claims recited non-elected SEQ ID NOS. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 133-134, 138-139, 143-144 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for boiling stable, detergent stable, protease resistant polypeptides that are (1) encoded by a polynucleotide of SEQ ID NO: 1 and/or (2) a polypeptide depicted as SEQ ID NO: 2 having a chaperone-like activity does not reasonably provide enablement for homologs of SEQ ID NOS: 1/2 to encode a polypeptide having chaperone-like activity and/or a polypeptide that has chaperone-like activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art to ascertain which homologs of instant SEQ ID NO: 2 function in the same way as the wild-type protein. Thus there could be thousands of variants which contain substitutions, deletions, additions etc. Thus for the instant claimed invention, it would require an undue burden of experimentation for a skilled artisan to determine exactly which homologs were active.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of

experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case the quantity of experimentation would be large since there are myriad substitutions, deletions or insertions to choose from. The amount of guidance in the specification is zero with regard to which amino acids in instant SEQ ID NO: 2 are essential for activity. No working examples are present of homologs of instant SEQ ID NO: 2. The nature of the invention is such that many different proteins that are substantially similar to instant SEQ ID NO: 2 may or may not be boiling stable, detergent stable, protease resistant, and/or have chaperone-like activity. The state of the prior art is that even proteins that are 99% similar to the wild-type protein are at times not fully active. The relative level of skill in this art is very high. The predictability as to what substantially similar protein will have which activity is zero. When the factors are considered in their entirety, the Wands analysis dictates a finding of undue experimentation and thus, the claim is not enabled.

Claims 133-134, 138-139, 143-144 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to boiling stable, detergent stable, protease resistant polypeptides having chaperone-like activity encoded by the polynucleotide depicted as SEQ ID NO: 1 or homologs thereof, and/or having the polypeptide sequence depicted as SEQ ID NO: 2 or homologs thereof, that have chaperone-like activity. *Vas-Cath Inc. V. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed."* The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." As stated above, the polypeptide of instant SEQ ID NO: 2 or homologs thereof, that have chaperone-like activity. However, the skilled artisan cannot necessarily envision the detailed structures of ALL of the homologs of the polypeptide depicted as instant SEQ ID NO: 2 that have the same functional activity as the wild-type polypeptide of instant SEQ ID NO: 2 because nowhere in the specification is it described which amino acids are even essential and critical for the wild-type protein to maintain its functionality, and therefor conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the methods of making the claimed invention. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or making it. The compound itself is required.. See *Fiers v. Revel*, 25

USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Claims 132, 135-137, 140-142, 145-146, 171-176 are rejected under 35 U.S.C. 112, first paragraph, because it refers to a protein only by function.

The court of Appeals for the Federal Circuit has recently held that such a general definition does not meet the requirements of 35 U.S.C. 112, first paragraph. "A written description of an invention involving chemical genus, like a description of a chemical species, requires a precise definition, such as be structure, formula {or} chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.,* 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). The court held that "in claims involving chemical materials, generic formulae usually indicate with specificity what generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish it from others. One skilled in the art therefore cannot, as one can do with a fully described genus visualize the identity of the members of the genus". Here, Applicants are claiming a product by what it does, i.e. function, rather than what it is, i.e. in terms of structure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 134, 139, 144, 171-176 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 134, 139, 144 recite at least 60% homologous to SEQ ID NO: 2. It is unclear if by "homologous", Applicants mean the polypeptide has at least 60% sequence identity to SEQ ID NO: 2. Further clarification is requested.

Claims 135, 140, 172 do not further limit the parent claims (claims 132, 137) because boiling stable polypeptides and/or protease resistant polypeptides are oligomers by inherency.

Claims 171, 173, 175 recite an additional peptide. The claims are unclear because they do not identify the additional peptide.

Claims 174, 176 are included in this rejection because they are dependent on claims 173, 175 and fail to cure the defect.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 132, 135-137, 140-142, 145-146 are rejected under 35 U.S.C. 102(a) as being anticipated by Wang et al. (October 30 2001 ISHS Acta Horticulture 560: IV International Symposium on In Vitro Culture and Horticulture Breeding, pages 285-292). Wang et al. teach BspA, a boiling-stable protein isolated from aspen that assembles to form an oligomer and has a chaperone-like activity (p. 288; claims 132, 135). Wang et al. further teach that the accumulation of BspA is stimulated by water stress, salt stress, osmotic stress, as well as temperature shifts (cold and heat shocks) (p. 288; claims 136-137, 140-141). Additionally, studies on the in vitro protection of heat-inactive citrate synthase and horseradish peroxidase demonstrated that BspA can function in stabilization of denatured enzymes (p. 288; claims 142, 145-146).

Claims 142, 145-146 are rejected under 35 U.S.C. 102(b) as being anticipated by Leung et al. (1996 Cell Stress and Chaperones 1(1): 78-89). Leung et al. teach heat shock cognate protein (Hsc70) is protease-resistant at 20°C, has chaperone activity, and protects and reactivates thermally inactivated enzymes (p. 78-79; claims 142, 145-146).

Claims 132-146, 171-176 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. (US 20050074763; IDS).

The applied reference has five common inventors with the instant application. The Oath/Declaration lists eight inventors for the instant application. Based upon the earlier effective

U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Wang et al. teach SP1, a boiling stable, detergent stable, and protease resistant protein having chaperone-like activity that is purified from aspen plants (p. 8 [0100]). Wang et al. also teach SEQ ID NOS: 1/2 (which has 100% sequence identity to instant SEQ ID NOS: 1/2) that describe a boiling stable, detergent stable, and protease resistant protein having chaperone-like activity, is natively an oligomer, and able to heat stabilize proteins (p. 27-28 claims 46, 56, 66; claims 132-146). Wang et al. further teach a fusion protein comprising boiling stable, detergent stable, and protease resistant protein having chaperone-like activity (p. 29 claim 84; claims 171-176).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

October 24, 2007

M. Monshi
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PRIMARY EXAMINER